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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/916,711 07/27/2001 Rathbun Rhodes 1146-8 8240

20995 7590 09/24/2003

KNOBBE MARTENS OLSON & BEAR LLP  
2040 MAIN STREET  
FOURTEENTH FLOOR  
IRVINE, CA 92614

EXAMINER

NASSER, ROBERT L

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 09/24/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/916,711

Applicant(s)

RHODES ET AL.

Examiner

Robert L. Nasser

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-15 and 21-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,9. 6) ☐ Other: \_\_\_\_\_

Art Unit: 3736

The examiner notes that the art from the IDS of 1/25/2002 has been separated from the case and requests that applicant re-submit any non-patent or non PCT references, as they are not readily available to the examiner.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I, drawn to figure 2a.

Species II, drawn to figure 2b.

Species III, drawn to figure 2c.

Species IV, drawn to figure 2d.

Species V, drawn to figure 2e.

Species VI, drawn to figure 2f.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-10, 12-15, and 21-33 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

Art Unit: 3736

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Rose Thiesen on September 2, 2003 a provisional election was made with traverse to prosecute the invention of species I, claims 1-10, 12-15, 21-33. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11 and 16-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The specification is objected to because the serial number is missing on page 22. Applicant should fill in the blank space.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 3736

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-4 are rejected in that claims 1 and 3 are substantial duplicates of claims 2 and 4. The only difference is an intended use recitation in the preamble which does not limit the claim. As such, both claims recite identical structure and are therefore duplicates.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-10, 12-15, and 22-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shults et al in view of Kawaguri et al. Shults et al shows a glucose sensing device including a housing made from polyethylene, (see column 9, lines 35-36), where the housing includes a sensing area having a working reference and counter electrode 20, 21, and 22, and a multi-layer membrane over the electrode area. The area of the counter and working electrodes appears to be the same. However, Kawaguri et al teaches that in order to stabilize the potential of the electrodes, it is desirable to have the counter electrode be twice the size of the working electrode (see column 4, lines 18-21). Therefore, it would have been obvious to modify Shults et al to use such an arrangement of working and counter electrodes, so as to stabilize the potential of the electrodes. The multi-layer membrane includes (from farther away to

Art Unit: 3736

adjacent to electrodes) an angiogenic layer which is equivalent to the disclosed cell disruptive domain, a second layer which is the bioprotective layer, which is equivalent to the cell impermeable domain, then an enzyme membrane comprised of a resistance layer, an enzyme layer, an interference layer, and an electrolyte (i.e. hydrogel layer).

The examiner notes that with respect to claim 6, the first domain is the angiogenic layer and the bioprotective layer. With respect to claim 7, the resistance layer is the second domain and excludes glucose. With respect to claims 8 and 9, the enzyme layer is the third domain. Both the working and counter electrodes are made from platinum (see column 9, line 62- column 10, line 2). The device of Shults is implanted. Shults further teaches the recited method.

Claims 1-5, 7, 10, 12, 13, and 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al 6119028 in view of Kawaguri et al. Schulman shows an analyte measuring device including a housing (see figures 6 and 7) including working, counter and reference electrodes 12, 14, 16, and 18, and a multi-layer membrane 20, 24, 34, 36, and 38. The area of the counter and working electrodes appears to be the same. However, Kawaguri et al teaches that in order to stabilize the potential of the electrodes, it is desirable to have the counter electrode be twice the size of the working electrode (see column 4, lines 18-21). Therefore, it would have been obvious to modify Schulman et al to use such an arrangement of working and counter electrodes, so as to stabilize the potential of the electrodes. With respect to claims 3 and 4, membrane 24 is made from silicone, which is disclosed to be the material used for the oxygen antenna domain. Hence, membrane 24 is an oxygen antenna. With

Art Unit: 3736

respect to claim 7, membrane 24 is a glucose exclusion membrane. Schulman shows the remaining claim features. With respect to claims 23 and 24, Kawaguri et al teaches that the working and counter electrodes are made from platinum. Hence, it would have been obvious to modify Schulman et al to use platinum, as it is merely the substitution of one known equivalent material for another.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shults et al in view of Kawaguri et al as applied to claims 12, 5-10, 12-15, and 22-33 above, and further in view of Ward et al et al. Ward et al shows an analyte sensing device with a housing made from ceramic. Hence, it would have been obvious to modify Shults et al to use ceramic, as it is merely the substitution of one known equivalent material for another.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Carter shows another device where the counter electrode 5 or 5a is larger than the working electrode 8 or 8a.

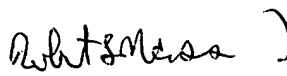
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Robert L. Nasser  
Primary Examiner  
Art Unit 3736

RLN

  
ROBERT L. NASSER  
PRIMARY EXAMINER